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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,793	04/14/2004	James J. Modliszewski	60310-USA	6666

7590 11/23/2009

Paul A. Fair - Patent Administration
FMC Corporation
1735 Market Street
Philadelphia, PA 19103

EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
11/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,793	MODLISZEWSKI ET AL.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 22-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *Mar. 30, 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed July 14, 2009 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claims 20 and 21 have been canceled;
(B) Claims 1, 3, 23 and 24 have been amended;
(C) Comments regarding Office Action have been provided drawn to:
  (I) the non-statutory obviousness-type double patenting rejection, which has been withdrawn in view the amendment to Claim 1;
  (II) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patent.

2. Claims 1-19 and 22-27 are pending in the case.

Information Disclosure Statement

3. The information disclosure statement filed March 30, 2009 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Please confirm that US-346,669 is the correct patent number. A copy of this document was not readily available at the time of this office action.

Claim Rejections - 35 USC § 103

New Ground of Rejection

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-17, 20, 21 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US Patent No. 6,214,376 B1, already of record) in view of Fonkwe et al (US Patent No. 6,949,256 B2, newly cited).

Applicants claim a delivery system comprising a homogenous, thermoreversible gel film, wherein said gel film comprises: (i) a film forming amount of kappa-2 carrageenan and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent; and (ii) an active substance, wherein said film: (1) comprises sodium cation, (II) has a solids content of at least 50% based on all components in the gel film, and (iii) has a break force strength of at least 1,000 grams.

The Gennadios patent discloses a gelatin-free capsule for use in oral administration of medicines, cosmetic or bath applications, or dietary supplements which can be prepared from compositions comprising (a) 8-50% by weight of water-dispersible or water-soluble plasticizer, (b) 0.5 to 12% by weight .kappa.-carrageenan, (c) 0 to 60% dextrins, and (d) 1% to 95% by weight water, with the .kappa.-carrageenan comprising at least 50% by weight of all gums forming or contributing to formation of thermoreversible gels in the composition (see abstract). The Gennadios patent discloses that a capsule for oral administration or cosmetic application may comprise a fill material to be

administered to a patient or subject, wherein the capsule comprises an aqueous based film comprising (a) water-dispersible or water-soluble plasticizer, and (b) carrageenan, with the carrageenan comprising at least 50% or 75% by weight of .kappa.-carrageenan, and the carrageenan comprising at least 50% or 75% by weight of all gums which form or contribute to the formation of thermoreversible gels (see abstract). This description of the gelatin-free capsule of the Genndios patent embraces the subject matter of instant Claims 1, 2 and 4-10. See column 2, lines 3 and 4 wherein the Gennadios patent discloses that Kappa Carrageenan is known to form gels in the presence of potassium cations, which embraces the subject matter of instant Claim 3. See column 3, lines 44-54, wherein the Gennadios patent discloses that carbohydrates such as glycerin, alkylene glycols, sorbitol, maltitol, lactitol, xylitol, corn syrup solids, and other polyols or combinations thereof can be used as plasticizers, which is identical to the plasticizers disclosed in instant Claim 13. See column 4, 2nd paragraph wherein the Gennadios patent discloses that mannan gums (e.g., locust bean gum, konjac gum, and tara gum) which have a synergistic gelling effect with .kappa.-carrageenan can be added to increase gel strength and elasticity. In this paragraph, Gennadios also discloses that part of the .kappa.-carrageenan may be substituted by iota-carrageenan (up to a maximum of 50% or 25% by weight of the .kappa.-carrageenan) which forms "softer" and more elastic gels. This description of the combination of .kappa.-carrageenan with other mannan gums and iota-carrageenan embraces the use of a second film former disclosed in instant Claims 12 and 13. The Gennadios patent further discloses that hydrolyzed starches, such as maltodextrin are added to (1) increase solids concentration in the gel mass (2) aid heat sealing by increasing wet film tackiness, and (3) prevent "hazing" of dried carrageenan capsules induced by the gelling salt and, if added, the mannan gums, wherein maltodextrin from corn starch is optionally used due to wide availability and low cost. The material added by Gennadios to increase solids concentration in the gel mass meet the requirement of using bulking agents in instant Claim 13.

The delivery system of the instant claims differs from the delivery system (capsule) of the Gennadios patent by claiming that the gel film thereof comprises

.kappa.-2 carrageenan as opposed to .kappa.-carrageenan used in the Gennadios patent.

However, the substitution of .kappa.-carrageenan with kappa-2 carrageenan is obvious since both compounds are classified as kappa-carrageenan and minor differences in the stability of gel strength between kappa-2 carrageenan and a similar amount of kappa-carrageenan/iota-carrageenan combination does not show unexpected results. Where the claimed and prior art compounds possess a close structural relationship and a specific significant property in common which renders the claimed compounds obvious to one skilled in the art, they are effectively placed in the public domain and unpatentable per se, even though the Applicant has discovered that they possess an additional activity. In re Mod et al. (CCPA 1969) 408 F2d 1055, 161 USPQ 281; Monsanto Co. v. Rohm & Haas Co. (DC Pen 1970) 420 Fsupp 950, 164 USPQ 556 (affd. On other grounds, 172 USPQ 323).

The instantly claimed delivery system also differs from the Gennadios patent by claiming that the film thereof has a break force strength of at least 1,000 grams.

The Fonkwe et al patent, which discloses a film-forming hydrocolloid composition comprising kappa-carrageenan, iota carrageenan, bulking agent, and plasticizer, reports that the tensile strength at rupture of a film made from the film-forming composition set forth therein having a moisture content of between about 5% and about 20% as being desirably between about 5 N and about 40 N, as measure by methods known to practitioners in the art (see column 4, lines 35-41). The Fonkwe et al patent discloses that one suitable means of measuring the tensile strength at rupture is by use of a TX-XT2 Texture Analyzer by Stable Micro Systems. The film tensile strength of 5 N to 40 N disclosed in the Fonkwe et al patent embraces the break force strength of at least 1,000 grams recited in instant Claims 1 and 14-17. Also see page 16, 2nd paragraph of the instant specification wherein a Texture Analyzer TA is used to measure the break force strength of films therein, which is embrace by the Texture Analyzer used to measure the tensile strength of the films disclosed in the Fonkwe et al patent.

One of ordinary skill in this are would be motivated to combine the teaching of the Gennadios patent with the teaching of the Fonkwe et al patent since both

documents disclose non-gelatin capsules made from compositions comprising carrageenans, plasticizers and bulking agents.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to used films in the delivery system of the Gennadios patent that have a break force strength of at least 1,000 grams in view of the recognition in the art, as evidenced by the Fonkwe et al patent, that such films provide improve contact between the encapsulating material and the solid tablet core.

6. Applicant's arguments with respect to Claims 1-17, 20, 21 and 23-27 have been considered but are moot in view of the new ground(s) of rejection.

7. Claims 18, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US Patent No. 6,214,376 B1, already of record) in view of Fonkwe et al (US Patent No. 6,949,256 B2, newly cited).

Applicants claim a process for preparing the homogeneous gel film delivery system comprising the steps of: (i) heating, hydrating, mixing, solubilizing and, optionally, de-aerating said kappa-2 carrageenan and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent in an apparatus providing sufficient shear, temperature and residence time to form a homogeneous molten composition, wherein said temperature is at or above the solubilizing temperature of said composition; (ii) adding an effective amount of an active substance either prior to or after formation of the molten composition; and (iii) cooling said molten composition containing said active substance at or below its gelling temperature to form said gel films containing said active substance.

The Gennadios patent discloses a process for forming the capsules (the delivery system) comprising heating the composition, casting or extruding the composition into a film, gelling the composition by cooling, associating a fill material with the gelled composition (usually as a film) and sealing the film about the fill material, wherein the capsules comprises a compositions comprising (a) 8-50% by weight of water-dispersible or water-soluble plasticizer, (b) 0.5 to 12% by weight .kappa.-carrageenan, (c) 0 to 60% dextrins, and (d) 1% to 95% by weight water, with the .kappa.-carrageenan comprising

at least 50% by weight of all gums forming or contributing to formation of thermoreversible gels in the composition (see abstract). Additions process information is provided in the Example in column 6, which discloses a .kappa.-carrageenan or a blend of .kappa.-carrageenan and iota-carrageenan/gelling salt/mannan gum/xanthan gum (if these materials are present) is dispersed, e.g., at ambient or at least slightly elevated temperature (higher temperatures, of course, usually being advantageous in the physical dissolution of most materials), in a plasticizer (or mixture of plasticizers). Optional additives (e.g., the maltodextrin, gum arabic and protein) are dissolved in water (preferably at about ambient temperature, but some slight elevation or reduction in temperature may be used) to form an aqueous solution. The aqueous solution is added to the .kappa.-carrageenan/plasticizer mixture to form a working composition. The working composition is heated, preferably with stirring to above 130º F to below the boiling point of the working mixture. The heated working composition can then be transferred or introduced for processing to a conventional gelatin encapsulation machine (films are formed by casting the solution on cooled rotating (e.g., metal such as steel) drums, the films are fed through a series of rollers to counter-rotating dies which form, cut and fill capsules of various sizes.

The process for preparing the delivery system of the instant claims differs from the preparaition of the delivery system (capsule) of the Gennadios patent by claiming that the gel film thereof comprises .kappa.-2 carrageenan as opposed to .kappa.-carrageenan used in the Gennadios patent.

However, the substitution of .kappa.-carrageenan with kappa-2 carrageenan is obvious since both compounds are classified as kappa-carrageenan and minor differences in the stability of gel strength between kappa-2 carrageenan and a similar amount of kappa-carrageenan/iota-carrageenan combination does not show unexpected results. Where the claimed and prior art compounds possess a close structural relationship and a specific significant property in common which renders the claimed compounds obvious to one skilled in the art, they are effectively placed in the public domain and unpatentable per se, even though the Applicant has discovered that they possess an additional activity. In re Mod et al. (CCPA 1969) 408 F2d 1055, 161

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One of ordinary skill in this are would be motivated to combine the teaching of the Gennadios patent with the teaching of the Fonkwe et al patent since both documents disclose non-gelatin capsules made from compositions comprising carrageenans, plasticizers and bulking agents.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to used films in the delivery system of the Gennadios patent that have a break force strength of at least 1,000 grams in view of the recognition in the art, as evidenced by the Fonkwe et al patent, that such films provide improve contact between the encapsulating material and the solid tablet core.

8. Applicant's arguments with respect to Claims 18, 19 and 22 have been considered but are moot in view of the new ground(s) of rejection.

Summary

9. All the pending claims are rejected.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623